

TrokaBone, TrokaBone Sternal
Premarket Notification Submission



510(k) Premarket Notification Submission:

Summary of Safety and Effectiveness

Date of Preparation: January 15th, 2007

MAR 07 2007

Submitter Information/ production site:

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Contract Sterilizer:

Sterigenics
SteriPro Lab & EO Facility

Contact USA

Pajunk USA
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German American Trade Center
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Establishment Registration Number: 9611612

Device Information:

Device Name: **TrokaBone**
Trade Name(s): **TrokaBone, TrokaBone Sternal**
Common Name: **Biopsy cannula**
Classification Name: **Instrument, Biopsy**
Classification Reference: **21 CFR §876.1075, April 1, 2006**
Establishment Registration Number: **9611612**
Regulatory Class: **II**
Product Code: **KNW, FCG**
Panel: **Gastroenterology/Urology**
Predicate Devices:

1. **K013692** TrapSystem, manufactured by MDTech
1. **K051506** Sterylab Bone Biopsy

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Device Description:

Pajunk's TrokaBone and TrokaBone Sternal puncture sets consist of a modular system for single and multiple extraction of bone and bone marrow samples. Equipped with an ergonomic handle and manufactured of highgrade stainless steel, TrokaBone shows a high stability.

Indications for use

Pajunk's TrokaBone puncture set consists of a modular system for the extraction of bone and bone marrow samples for histological examinations.

The TrokaBone Sternal device is intended for the aspiration of bone marrow from the sternum area.

Predicate Devices:

Predicate devices with the same indications of use are:

2. **K013692** TrapSystem, manufactured by MDTech
3. **K051506** Sterylab Bone Biopsy

The detailed description of substantial equivalence outlining relevant parameters can be found in Section 12 of this submission.

Sterilization, Shelf life

Pajunks TrokaBone and TrokaBone Sternal are serilized with EO-gas.

The sterilization process is validated regularly. LAL-Pyrogene-testing, residual testing acc. to ISO10993-7 and bioburden testing are conducted quaterly with differing (worst-case) products.

The contract sterilizer and the sterilizing process is the same as used for all Pajunk Products already cleared for market.

The shelf life is validated for several worst case products (via real time aging) and set to 5 years.

Packaging and Labeling

Packaging and labeling procedures are identical to the procedures employed for several of Pajunks products already cleared for market by the FDA.

Packaging materials (cardboard, tyvek, hardblister) are identical to those employed for several of Pajunks products already cleared for market by the FDA.

Therefore packaging and labeling are claimed to be approved by FDA. Safety and effectiveness have been demonstrated for several years now.

Technology Characteristics:

Pajunk's TrokaBone puncture set consists of a modular system for single and multiple extraction of bone and bone marrow samples. This set offers a high degree of operational comfort during puncture and aspiration. Equipped with an ergonomic handle and manufactured of highgrade stainless steel, TrokaBone distinguishes itself from similar products due to its high stability.

Puncturing of the pelvic crest can be performed with either the bevel (hollow curve) or trocar tip. The puncture cannula is advanced forward into the bone wall by an alternating clockwise / counterclockwise movement under constant pressure. The stylet is removed as soon as the wall has been penetrated and the resistance has diminished.

The outer cannula has a very sharp "wave" shaped tip. With this tip, and a twisting motion, the cannula easily penetrates the inner structure of the bone. The tip of the cannula is designed

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cylindrically, tapering out towards the forward end. This makes the gathering of the sample and its extraction easier. At the same time, the conical shape ensures that the sample remains unchanged in its structure during tissue retrieval.

The ejection stylet is introduced and advanced into the distal opening of the outer cannula using an introductory aid. The sample can then be extracted.

The use of an inner cannula with biopsy chamber is recommended if more than one biopsy samples are required. This inner cannula takes up the sample during advancement, and it can be retracted for extraction without altering the placement of the outer cannula.

Biocompatibility:

Pajunks TrocaBone consists of materials and components already cleared for market and proven biocompatibility in several tests. Additionally special testing has been conducted for irritation (ISO10993-10), sensitization (ISO10993-10) and cytotoxicity (ISO10993-5) according to ISO10993-1.

Conclusion:

The comparison between the predicate devices and the proposed devices in section 12 of this submission as well as the validated sterilization process demonstrates that the proposed devices are substantially equivalent to the predicate devices and safe and effective.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Pajunk GmbH Medizintechnologie
% Christian Quass
Director Regulatory Affairs
Karl-Hall-Strasse 01
78187 Geisingen Germany

MAR 07 2007

Re: K070179

Trade/Device Name: TrokaBone
TrokaBone Sternal
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: FCG
Dated: February 26, 2007
Received: February 28, 2006

Dear Christian Quass:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

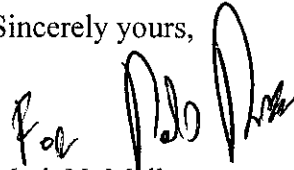
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forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', is written over the typed name.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for use

510(k) Number:

Device Name: TrokaBone

Indications for Use:

Pajunk's TrokaBone puncture set consists of a modular system for the extraction of bone and bone marrow samples for histological examinations.

Prescription Use **X**
(Per 21 CFR 801.109)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number

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Indications for use

510(k) Number:

Device Name: TrokaBone Sternal

Indications for Use:

The TrokaBone Sternal device is intended for the aspiration of bone marrow from the sternum area.

Prescription Use **X**
(Per 21 CFR 801.109)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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